

**NALSAR PROXIMATE EDUCATION
NALSAR UNIVERSITY OF LAW, HYDERABAD
P.G.DIPLOMA IN PATENTS LAW**

2013-14

Paper II – Practical

(Exploitation of Patents – Drafting, Specification & Patent Writing)

Time: 2 ½ hours.

TOTAL MARKS: 90

INSTRUCTIONS TO CANDIDATES

- 1. The questions to be interpreted as given and no clarification can be sought from the invigilator.**
- 2. Do not draw or attach figures**
- 3. Do not write detailed description or figure no.s**
- 4. The claim drafting will carry 30 marks**
- 5. The rest of the specification will carry 60 marks**
- 6. Attempt only one choice – either A or B**

Draft a Patent based on the information given by the inventor as below:

Option A

Keshav Murthy is a motorcycle enthusiast and owns several different motorcycles. He found that all motorcycles come integrated with a conventional side kickstand that provides support to the vehicle in a leaning position. When storing for a long duration, the side kickstand weakens and becomes unstable. Also it does not provide adequate support on soft ground, sloping surfaces or windy conditions. Keshav searched, in the market and also on the internet, for a good auxiliary stand that could help him park his motorcycle safely in an upright position in different parking conditions and could also be used with any of the different brands of motorcycles that he owned. He couldn't find any device that could satisfactorily solve his problem. He decided to solve this problem and worked on an invention which could provide auxiliary support to parked two-wheelers. He wants to file a patent and provides you with the following details. You are required to draft a complete specification for filing a National Application in Indian Patent office.

Two-wheeled motor vehicles are not generally able to maintain an upright position during parking or storage unlike four-wheeled vehicles. Many two-wheeled vehicles incorporate integral hinged kickstands which are selectively deployable along a side ground surface portion of the vehicle for providing support to the vehicle in a leaning position.

While the stand allows the vehicle to remain stable in a leaning position, on solid ground it does not provide stable support on soft ground, sloped surfaces or windy conditions. It

also fails to provide stability in several directions. Further pressure or movement along the hinge may lead to the collapse of the kickstand. Storage of long duration may also weaken the kickstand. Falling of the vehicle can often lead to costly aesthetic and mechanical damage to the vehicle.

Several work-stands exist for stabilizing the vehicle by raising the wheels above the ground for maintenance or repair which are not portable. Some attempts have been made for auxiliary parking attachments which suffer from several drawbacks. They are not suitable for engaging a vehicle in a variety of positions, offer only marginal improvement in stability, or require extensive alterations on the bike prior to deployment. Further they are not flexibly designed for use in different motorcycles.

For Keshav the options available in the market were not satisfactory.

He proposes an auxiliary jack stand providing for added stability to a parked two-wheeled vehicle. The device would engage a suitable structural portion of a vehicle using a top adaptor portion. The height of the apparatus can be adjusted using telescoping members and to collapse the telescoping system for transport and storage. A spring in the inside space portion of the telescoping assembly assists in the deployment of the system.

A locking and adjusting means to the telescoping assembly is provided by a ratchet and pawl assembly comprising a housing, a pawl, a spindle and a pawl spring manipulated by use of an adjusting knob.

Several top adaptors are present which can be selectively attached or removed to the top of the telescoping assembly using via a pin and detent ball system. The adaptor would engage a suitable circular structural member of the vehicle to provide auxiliary support on either side of the motorcycle. The adaptors would be configured to commonly manufactured brand-name motorcycles available commercially.

An adjustable ball jointed foot pad assembly would be placed on the ground surface. Eccentric mount of the base footpad enables adjustable positioning relative to the degree of the inclination of the ground. Ball joint connection to the telescoping assembly enables adjustment of the foot in all three dimensions. Different foot portions are also available for secure engagement with the ground. These may be enhanced with anti-skid configuration or material, serrated surfaces, cleats or the like.

Many styles, embodiments and configurations are made possible without deviating from the basic concept of the invention.

One method of using the apparatus would be to choose a parking place for the vehicle, and parking the motorcycle using the kickstand. The rider then evaluates the ground conditions and slope, and choosing an appropriate structural member of the vehicle, identifies the appropriate top adaptor. A suitable foot assembly is selected and the required length of the system is measured. The system is inserted under the vehicle and final length adjustment is made. The adjusting knob is used to set the ratchet to the locking position. The stability of the vehicle is ascertained. When the vehicle is removed from parking, the ratchet is set to releasing position and the device is removed and collapsed for storing and transportation.

FIGURES – Option A

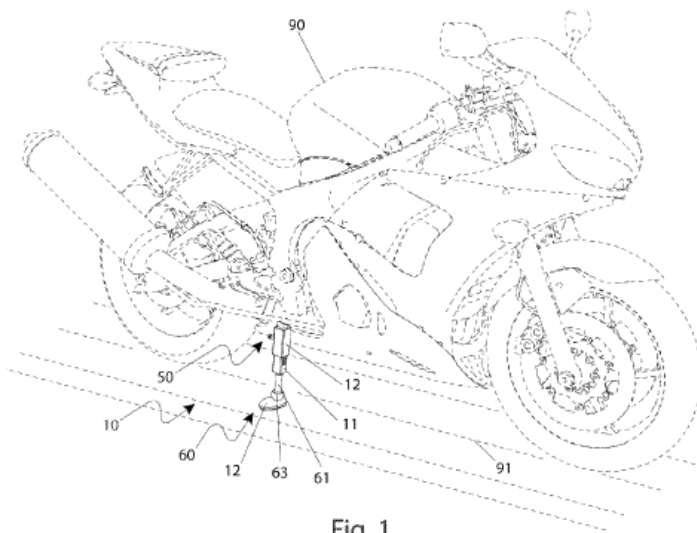


Fig. 1

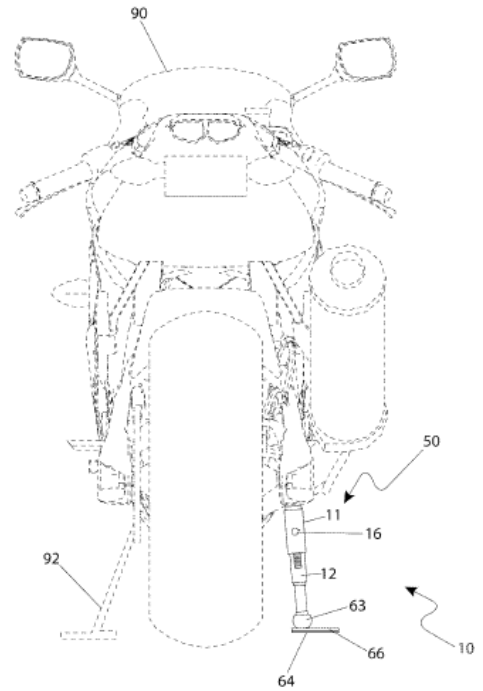


Fig. 2

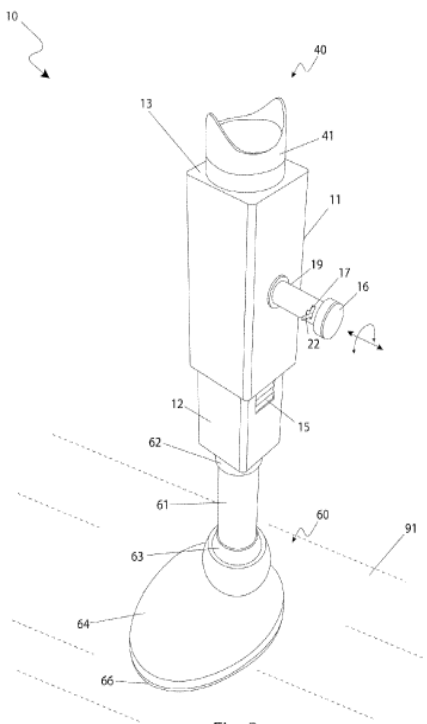


Fig. 3a

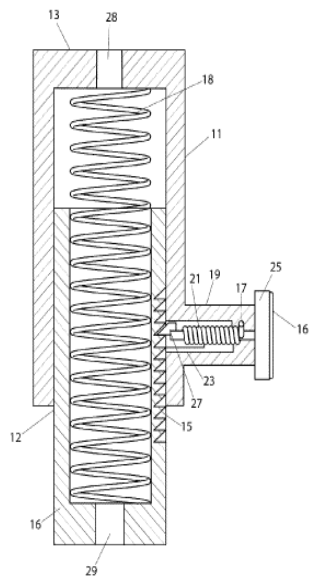


Fig. 3b

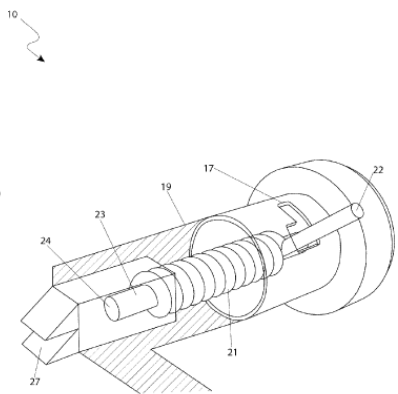


Fig. 3c

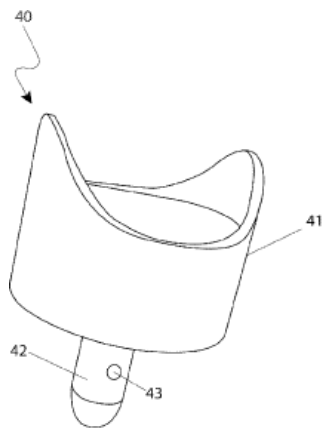


Fig. 4a

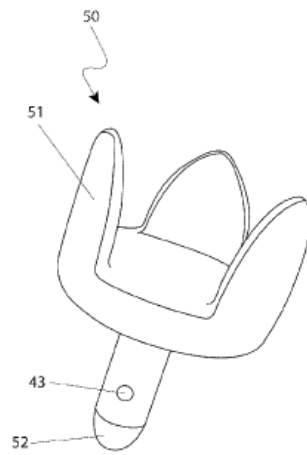


Fig. 4b

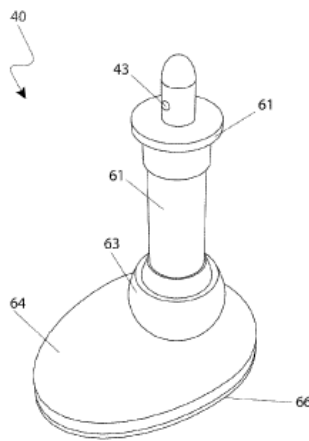


Fig. 5a

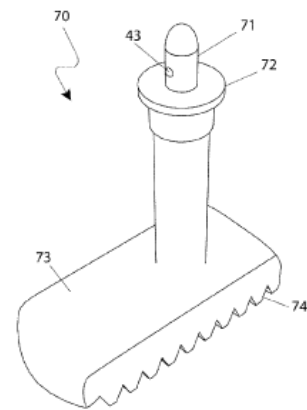


Fig. 5b

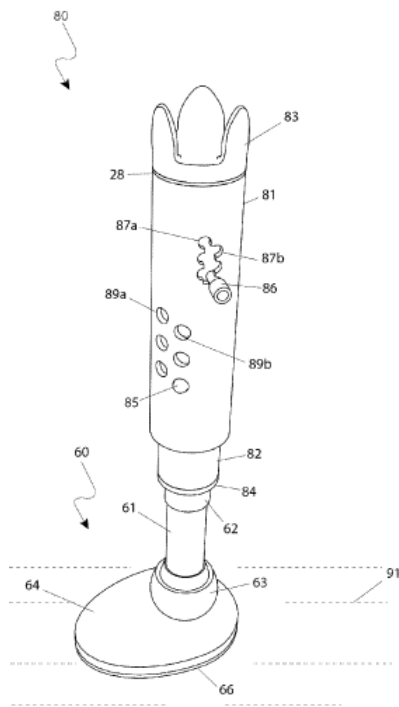


Fig. 6a

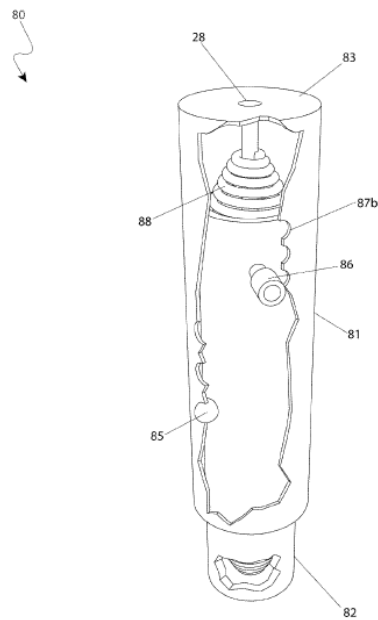


Fig. 6b

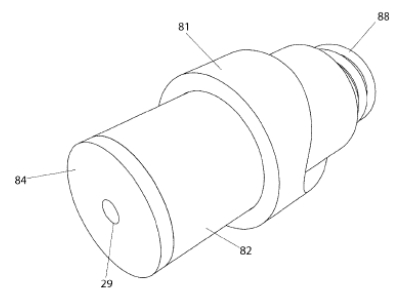


Fig. 6c

Option B

Tengler Scientific Institute has been working on liquid sustained release formulations that improve ease of ingestion in paediatric and geriatric patients, and provide better bioavailability than solid dosage forms. They have invented a composition and method of making a shelf-stable liquid formulation comprising active agents bound in controlled-release microbeads in a dense thixotropic solution. The Chief Technical Officer of the Institute has approached you for assistance in filing a patent and provides you with the following disclosure. You are required to draft a complete specification for filing a National Application in Indian Patent office.

Several problems are associated with the manufacture of liquid, sustained release formulations. Many of the materials and processing methods and equipment used in the industry today fail to provide liquid sustained release formulations that are shelf-stable, do not separate on the shelf (both floating and settling), or do not require vigorous shaking (thereby affecting dosing consistency). The liquid product has poor mouth-feel (e.g., grainy, bitter, slimy) and does not provide actual controlled, sustained, mixed or modified release. Further, liquid, controlled release formulations have not been amenable to large scale production in facilities and amounts that are permissible for industrial applicability. Many known techniques for overcoming the above problems, such as inert gas sparging, vacuum and reducing mixer speeds, have not solved the problems.

The present invention eliminates some of the associated problems such as preventing shear and breakage of microbeads destroying their sustained-release nature, and formation of bubbles that form on or cling to the beads thereby changing their nominal density. The invention teaches a method of preparing a dense thixotropic solution having a density that is at or about the density of one or more microbeads. The thixotropic solution comprises water, preservatives and a thixotropic agent, mixed under conditions that reduce bubble formation, e.g., using a mixer that lacks scraping paddles.

The microbeads may include an enteric coating, a resin coat, a lacquer coat, a pH-sensitive coating, a biodegradable polymer matrix, a water soluble matrix, an ionic matrix, or a combination or mixture of the above. Microbeads may also include polymers such as, but not limited to, cellulose, ethylcellulose, methylcellulose, propylcellulose, methoxypropylcellulose, cellulose nitrate, polyvinyl alcohol, polyvinyl chloride, polystyrene, polyethylene, polystyrene, polyacrylate and salts, and/or combinations and mixtures of the above.

The method of the invention increases the shelf-life and stability of the active agents in several ways, including by preventing the separation of the components by eliminating bubble formation. Bubble formation may be eliminated or reduced by the following steps alone or in combination: using a diaphragm pump to combine the constituents, by placing the recirculating tube below the surface of the liquid, by adding liquids along the side of the vessel holding the liquid, sprinkling beads on the surface of the mixture, mixing the solution in the absence of one or more scraping paddles, using a propeller mixer at a speed that reduces or minimizes cavitation, and a combination of the above.

The formulation may include a portion of the one or more beads with an immediate release profile and another portion with delayed release profile. A person skilled in the art would

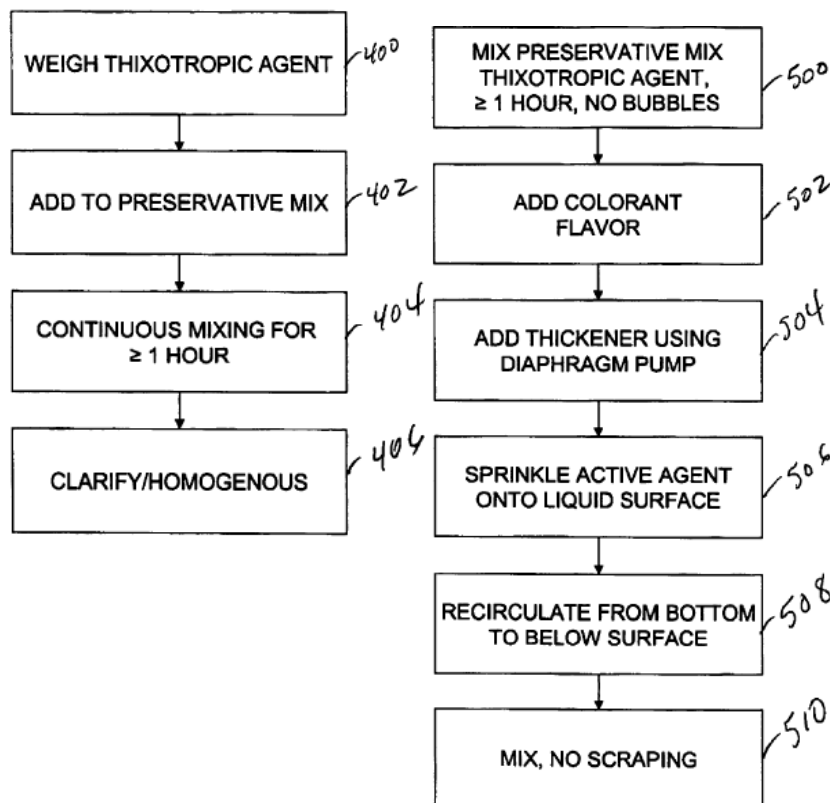
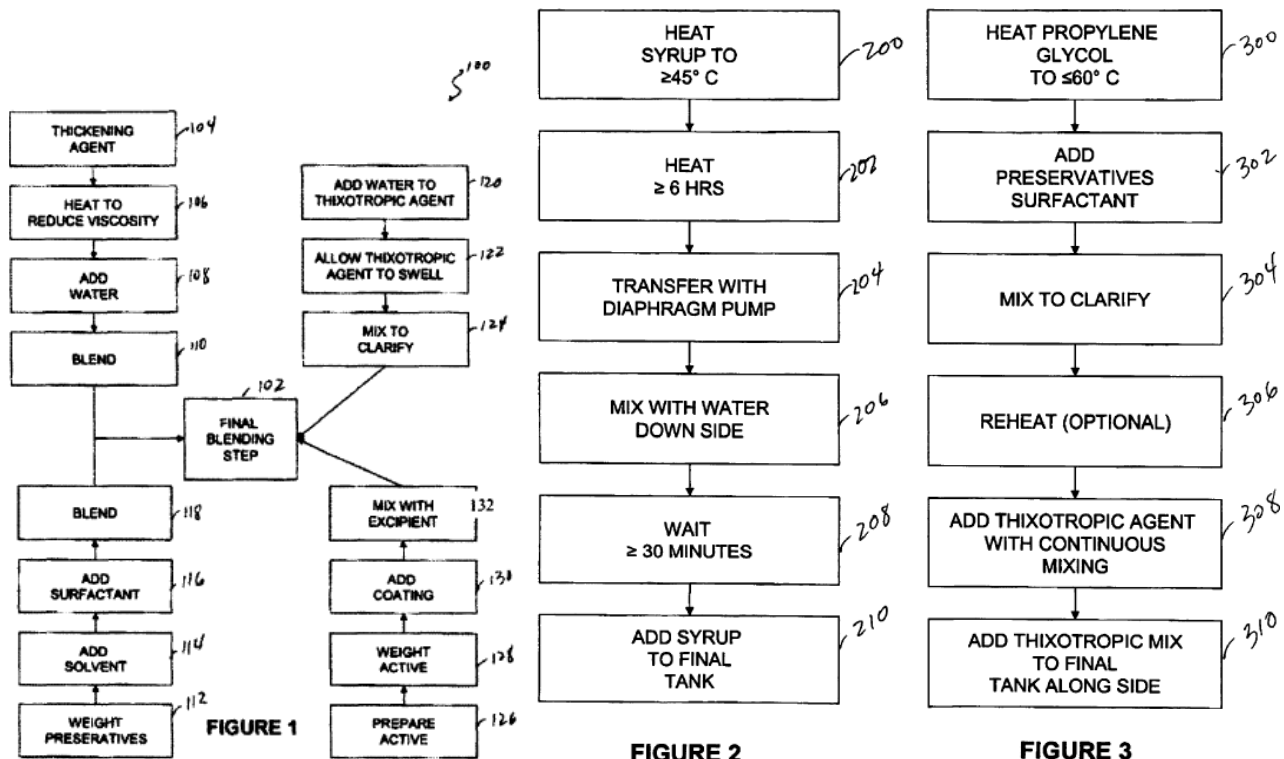
be able to determine the amount of loading (theoretical and empirical), and the conditions for retention and release based on the ion-exchange matrix, bead or resin used to retain the active agent. The liquid formulation may be of low ionic strength depending on the nature of the matrix and active agent.

Active agents may be in the form of nutritional supplements, herbal extracts, gums, oils, salts, mixtures and combinations thereof. APIs may include proteins, peptide, carbohydrate, poly saccharide, glycoprotein, lipid, hormone, growth factor, cytokine, interferon, receptor, antigen, allergen, antibody, antiviral antifungal, antihelminthic, substrate, metabolite, cofactor, inhibitor, drug, nutrient, toxin, poison, explosive or pesticide. The active agent may be a pharmaceutical agent, an enzyme, a cytokine, a growth promoting agent, an antibody, an antigen, a hormone, a vaccine, a cell, a live-attenuated pathogen, a heat-killed pathogen, a virus, a bacteria, a fungi, a nucleic acid or combinations and mixtures thereof. Specific examples may include steroids, respiratory agents, local anesthetics, antihypertensive agents, vasoconstrictors, beta-blockers, herb extracts, muscarinic cholinergic agents, anorectic drugs, antitussives, expectorants, analgesics or even a narcotic.

For example, a liquid formulation made by methods disclosed in this invention may be used for treating cold/cough or allergy using one or more of the following: anti-tussives, anti-histamines, expectorants and analgesics. For example, the actives may include pseudoephedrine, chlorpheniramine, dextromethorphan, guaifenesin and salts thereof or mixtures of salts thereof.

A liquid controlled-release formulation may be made by blending one or more controlled release beads having active agents with a dense thixotropic solution or with a thickening agent and a surfactant by mixing with a low cavitation propeller and recirculating the mixture under the surface of the mixture to minimize bubble formation. Another method of preparing a liquid controlled-release formulation may be by blending a mixture comprising the active agent on or about a carrier, a thickening agent under conditions that minimize the introduction of air. The steps may include using a diaphragm pump to combine the water and the thixotropic agent, preservatives, colourants, and flavourants; placing the recirculating tube below the surface of the liquid, adding liquids along the side of a vessel, sprinkling beads onto the surface of the liquid, mixing the solution in the absence of a scraping paddle and at a speed that reduces or minimizes cavitation. Another method may include blending the microbeads with one or more active agents on a carrier in a solution having a low ionic concentration and a thixotropic agent under conditions that minimize the introduction of air bubbles.

FIGURES - Option B



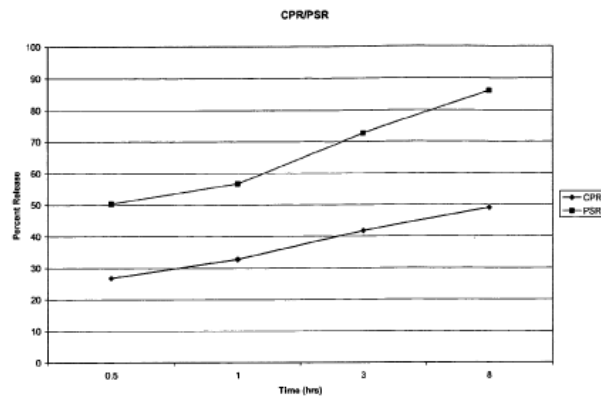


Figure 6

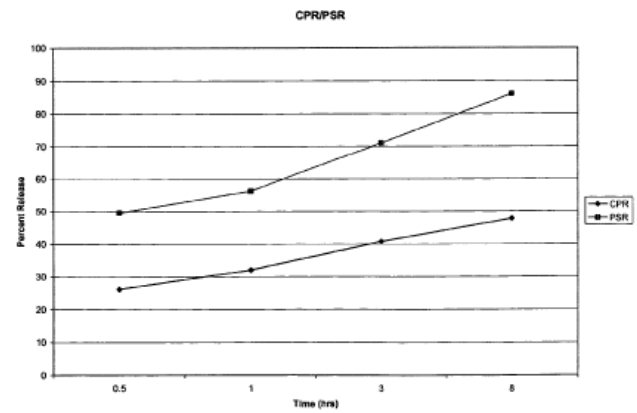


Figure 7

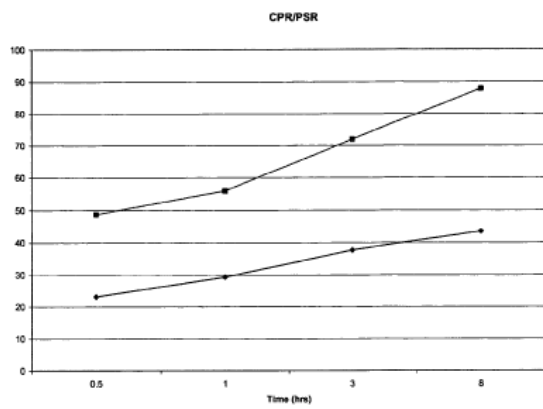


Figure 8

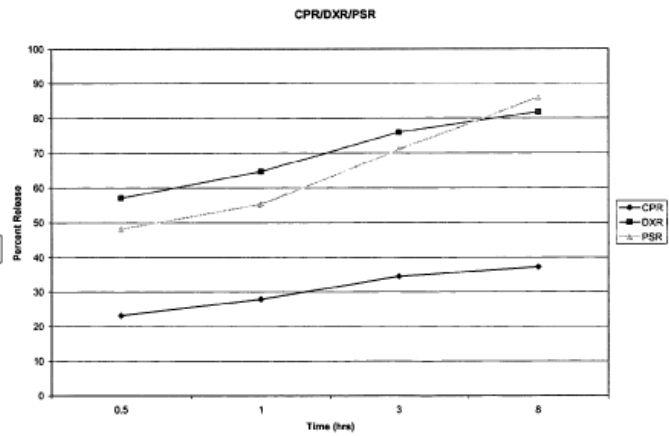


Figure 9

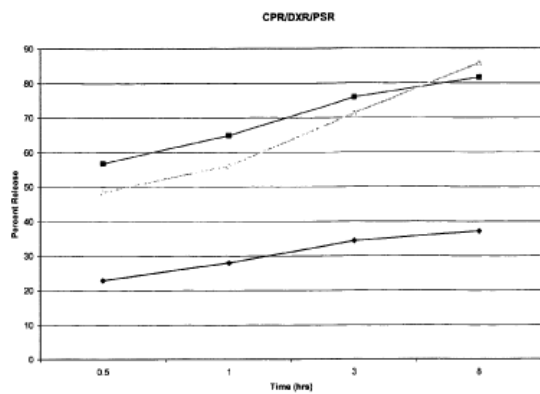


Figure 10

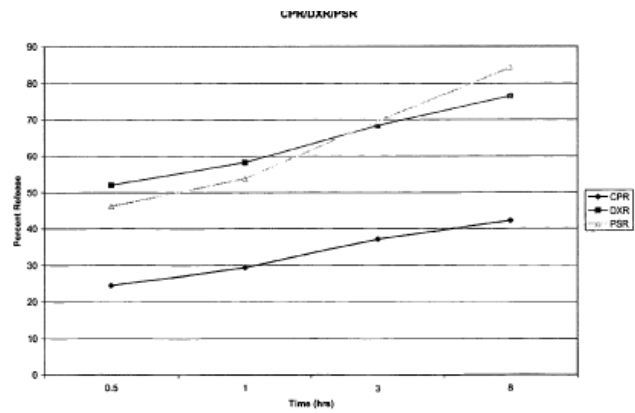


Figure 11